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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/730,663	12/06/2000	Michael J. Hageman	01-677	8091

7590 06/07/2002
PHARMACIA CORPORATION
PATENT DEPARTMENT - 04B
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ST LOUIS, MO 63167

EXAMINER

SHAMEEM, GOLAM M

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 06/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/730,663

Applicant(s)

HAGEMAN ET AL.

Examiner

Golam M M Shameem

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 2-14 and 16-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 & 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Status of Claims

Claims 1-26 and 35-38 are pending in this application. In response to the restriction requirement of paper No. 6, Applicants have elected Group I, claims 1 and 15 drawn to a compound and composition of celecoxib without traverse for prosecution.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections, set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Talley et al (US Pat. No. 5,466,823).

Determination of the scope and content of the prior art (MPEP §2141.01)

Talley et al teach a class of pyrazolyl benzenesulfonamide compounds and its pharmaceutical composition for treating inflammation and inflammation-related disorders.

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Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Applicants claim a pharmaceutical composition comprising an amorphous celecoxib having enhanced bioavailability. The generic compound, its chemical formula and composition taught by Talley et al are similar of applicant's compound (see column 39, example 21). The sole difference between the claimed compound and that of the reference herein lie in the physical state/form of compound (amorphous versus other) and therefore its composition. There is no patentable distinction in the concept of a chemical compound in crystalline form over the same compound its amorphous form. In re Weijlard, 69 U.S.P.Q. 86, 87 (C.C.P.A. 1946). Further, changing the form, purity or other characteristics of an old product does not render the novel form patentable where the difference in form, purity or characteristics was inherent in or rendered obvious by the prior art. In re Cofer, 148 U.S.P.Q. 268 (CCPA 1966). In the absence of a showing of a viable unexpected property, the instant claimed invention is found obvious. Applicants should note that a generic teaching is grounds for 35 USC § 103 obviousness type of rejection.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

It would have been prima facie obvious to one having ordinary skill in the art at the time of the invention was made since Talley et al teach compounds that are of the same identical formula and as such would be expected to have the similar utility. The difference, if any, may reside in there being different amorphous forms. One skilled in the art would have been motivated to prepare different amorphous forms of known pharmaceutically useful compounds with the expectation of obtaining a pharmaceutically useful benefit, such as treating a medical condition or disorder etc. Products which are merely different forms of known compounds, notwithstanding that some desirable results are obtained therefrom, are unpatentable where

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products have same utility as the art compounds. Ex parte Hartop, 139 USPQ 525, 1963. Mere change of form in and of itself does not disclose novelty. Ex parte Conn and Norman, 119 USPQ 388, 1956. Therefore, absent a showing of unobvious and superior properties, the instant claimed amorphous forms of a known compounds would have been suggested to one skilled in the art.

Hamley et al and Simitchieva are cited to show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (703) 305-0116. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (703) 308-4532. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592. When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

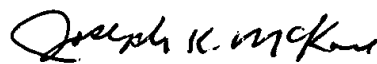
Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy

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published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG
89.

Any inquiry of a general nature or relating to the status of this application should be
directed to the Group receptionist, whose telephone number is (703) 308-2286.

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Joseph K McKane
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June 6, 2002